

REMARKS

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections, and allow claims 1, 6, 8, 10, 12-16, 19, 23, 25-26, the currently pending claims. The amendments to the claims correct dependency, antecedent basis, and rewrite Claim 10 in independent form. The amendments put the claims in better form for allowance or appeal. No new matter is added.

Amendments to the Brief Description of the Drawings are made herewith.

The Office Action states that the restriction requirement has been made final. Applicants reserve the right set forth in 37 C.F.R. 1.114 and M.P.E.P. 818.03(c) to petition the Commissioner for review of the requirement, which petition may be deferred until after final action on or allowance of claims to the invention elected. Applicants respectfully submit that the distinct anti-viral sequences share a common structural feature, and that a generic claim is appropriate.

As stated in the MPEP 803.04, "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). It has been determined that **normally ten sequences constitute a reasonable number** for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined."

Claims 1, 6, 8, 10, 12-16, 19, 21, 20, 23 and 25-26 have been rejected under 35 U.S.C. 112, second paragraph. The antecedent basis for the limitation "human cytomegalovirus genetic sequence" has been corrected. The dependency of Claims 19, 23 and 26 have been corrected. Withdrawal of the rejection is requested.

Claims 1, 6, 12-16 and 25-26 have been rejected under 35 U.S.C. 112. The Office Action states that the claims do not reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. It is stated that the specification fails to disclose a representative number of NA polynucleotide ligands having hCMV activity. Applicants respectfully submit that a representative number of species has been provided. Regardless of current restriction practice, one cannot properly

ignore data provided in the specification that is relevant to the claimed invention, and Applicants have provided three separate examples of sequences have demonstrated anti-viral activity.

The law regarding enablement of inventions is clear: “[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.”

The specification on page 10, line 13 discloses guidance for selecting polynucleotides through rounds of exponential enrichment. The specification gives guidance on how to determine whether a polynucleotide inhibits hCMV infection as set forth in the Examples, and in the specification, page 15, lines 12-24.

Specific examples of polynucleotide ligands meeting the requirements of the claims are provided, for example, in Tables 1 and 2, including L13, L19 and L66.

Applicants respectfully submit that the presently claimed invention meets the requirements of 35 U.S.C. 112, first paragraph.

Claims 1, 6, 8, 12-16, 21 and 25-26 have been rejected under 35 U.S.C. 112, first paragraph. Applicants respectfully submit that the presently claimed invention meets the requirements of 35 U.S.C. 112. The Office Action states that claims 8 and 21 are not enabled because the specification does not show they possess antiviral activity. Applicants respectfully submit that the sequences set forth in SEQ ID NO:12-16 meet the requirements of 35 U.S.C. 112.

As stated in the specification, (page 16, lines 27-30) 28 sequences coding for ligands after 16 rounds of selection were cloned and characterized (Table 1). In Figure 1B, the increase in binding affinity with cycles of selection is shown. Starting from nearly 0 at G0, the ligands are increased in affinity by nearly 5 orders of magnitude at G16. Binding affinity is stated to be an important attribute, and the specification states “In our study, the selected ligands exhibited a high affinity to HCMV particles and were highly effective in inhibiting viral production.” (page 22, line 32 to page 23, line 1)

The specification further states that “the binding affinity of the ligands also appeared to correlate with their activity in inhibiting viral infection. For example, the G16 ligands exhibited higher affinity to HCMV and were more effective in blocking viral infection than the G10 and G0 ligands.” (page 23, lines 1-3)

The Office Action states that there is no correlation between hCMV binding and antiviral activity. However, the ligands that are stated to lack antiviral activity are unrelated to the presently claimed sequences. The sequences presently claimed both share specific sequence motifs, e.g. the terminal TGGG sequence, and the internal motif purine-CCC(AT/TA), as well as other similarities. So that these sequences were not only selected for high binding affinity, but share sequence similarities with a sequence shown to have antiviral activity.

In addition to the function of blocking viral infection, the polynucleotides of the invention find use in identifying viral glycoproteins. HCMV, one of the largest human viruses, has the coding capacity for more than 220 open reading frames, 57 of which have been predicted to encode membrane proteins. To date, however, fewer than 10 virion envelope glycoproteins have been mapped to the viral genome and only four of them (gB, gH, gL, gO) have been implicated to be essential for viral entry. Identification of new viral essential glycoproteins will further our understanding of HCMV infection and provide novel targets for drug development.

The specification therefore provides sufficient enablement such that one of ordinary skill in the art would be able to practice the invention without undue experimentation. In view of the above amendments and remarks, withdrawal of the rejection is requested.

In view of the above amendments and remarks, withdrawal of the rejections is requested.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number BERK-005.

Respectfully submitted,
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